

# PSJ3

## Exhibit 302



# Order Monitoring System (OMS)

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Purdue OMS Program

NACDS Meeting

October 21, 2013

# Mission of the Purdue OMS Program

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To ensure compliance with DEA regulations requiring manufacturers and distributors to monitor and report suspicious orders of controlled substances, by implementing a detailed process for:

- ❑ Ongoing assessment of selected accounts, including Purdue's authorized distributors and their retail customers
- ❑ Support for authorized distributors in implementing their OMS programs and efforts to “know their customers”
- ❑ Reporting of suspicious ordering to DEA, other law enforcement, or state licensing boards, as appropriate

# History of the Purdue OMS Program

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- ❑ Followed DEA correspondence to all registrants detailing obligations of manufacturers and distributors of controlled substances to:
  - ❑ Conduct independent analysis and exercise due diligence to confirm legitimacy of orders and to scrutinize suspicious circumstances
    - ❑ Valid DEA registration not sufficient
    - ❑ Know your customers and your customers' customers
  - ❑ Inform DEA of suspicious orders when discovered
- ❑ Expanded program launched in 2008
- ❑ SOP finalized in March 2009

# Meetings with Distributors/Chains

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- ❑ ABC: Sept 2008; Nov 2011
- ❑ ANDA: Sept 2009
- ❑ Cardinal: Sept 2010; Nov 2012
- ❑ Harvard: Aug 2010
- ❑ HD Smith: Sept 2009; July 2012
- ❑ Kinray: April 2010
- ❑ Miami Luken: Aug 2010; Sept 2010
- ❑ Rochester: July 2013
- ❑ Valley: Jan 2009
- ❑ Walgreens: July 2013

# OMS Information Sources

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- ❑ Fee For Service (FFS) Data (covers 97%)
  - ❑ Order data for pharmacies + other dispensing outlets
  - ❑ Provided by authorized distributors under FFS Agreements
  - ❑ Loaded on monthly basis into OMS Database
- ❑ Distributors Data
- ❑ IMS outlet/prescriber data & Sales Ops outlier analyses
- ❑ Sales Force reports of concern (ROC)
- ❑ Government agencies/law enforcement
  - ❑ DEA, law enforcement, state licensing boards, legislative contacts
- ❑ Media reports

# Identify Potential Problematic Outlets

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- ❑ Orders of Outlets that Meet Pre/Post Reformulation Algorithm
- ❑ IMS Data Outliers (Outlets identified analysis of IMS Data)
- ❑ Outlets identified by Other Signals
  - ❑ Authorized distributor data on other opioid dispensing by pharmacy
- ❑ Collaboration with Authorized Distributors
  - ❑ Anomalies of pharmacy location, operation, orders, prescribers

# Algorithm - Identify Potential Problematic Outlets 2009 to 2010

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- ❑ Outlets with orders outside normal range based on algorithm:
  - ❑ Total volume of Purdue product orders
  - ❑ Percentages of OxyContin/non-OxyContin orders to total Purdue products
  - ❑ Percentages of orders of higher dosages of OxyContin
  - ❑ Number of distributors from which outlet purchases
  - ❑ Number of orders of same product per day
  - ❑ Significant changes comparing current 3, 6 & 12 months to prior period



# Updated Algorithm Post Reformulation 2010 to 2011

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- ❑ Outlets with decline in orders post OxyContin reformulation
  - ❑ Orders that met original algorithm
  - ❑ Significant declines/changes comparing current 3, 6 and 12 months of pre- versus post-reformulation data
  - ❑ Threshold 50% decline post reformulation
  - ❑ Percentage of OxyContin decline post reformulation vs contemporaneous increase in other opioids
  - ❑ Evaluate whether geographically located near prescribers of concern
  - ❑ Adjust threshold (\$350,000) to review significant accounts

## Additional Metrics from Data Report

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- ❑ Sales per outlet/account for each item in product family
  - ❑ Metric #1: Compare each outlet's total sales to state's average/outlet sales for the product family
  - ❑ Metric #2: Look at each outlet's share of the state's total volume of the product family
  - ❑ Metric #3: Look at highest dosage for potential abuse product's share (e.g. 80 mg for OXY) of outlet's total brand family purchases
  - ❑ Any outlet that has sales greater than 1 Standard Deviation above the averages on any of the 3 metrics above gets added to the product family's selection list for review
  - ❑ Select from the review list accounts for individualized review

# Example of Data Analysis

wholesaler	4 VS 4	% of change	Product	Current 4 mons	Mar-13	Feb-13	Jan-13	Dec-12	Product	Last 4 mons	Nov-12	Oct-12	Sep-12	Aug-12
CARD	19	100%	OTR810	19	19	0	0	0	OTR810	0	0	0	0	0
WALG	(64)	52%	OTR810	60	0	14	31	15	OTR810	124	31	38	31	24
<b>TI OXY 80</b>	<b>(45)</b>	<b>36%</b>	<b>TL OXY 80</b>	<b>79</b>	<b>19</b>	<b>14</b>	<b>31</b>	<b>15</b>	<b>TL OXY 80</b>	<b>124</b>	<b>31</b>	<b>38</b>	<b>31</b>	<b>24</b>
CARD	1	100%	OTR610	1	1	0	0	0	OTR610	0	0	0	0	0
WALG	(10)	59%	OTR610	7	0	5	2	0	OTR610	17	7	6	2	2
CARD	9	100%	OTR410	9	2	2	2	3	OTR410	0	0	0	0	0
WALG	10	100%	OTR410	10	10	0	0	0	OTR410	0	0	0	0	0
CARD	(33)	49%	OTR310	35	0	16	12	7	OTR310	68	14	19	18	17
WALG	6	100%	OTR310	6	6	0	0	0	OTR310	0	0	0	0	0
CARD	(9)	28%	OTR210	23	0	5	13	5	OTR210	32	9	11	7	5
WALG	12	100%	OTR210	12	12	0	0	0	OTR210	0	0	0	0	0
CARD	(54)	59%	OTR510	38	0	8	21	9	OTR510	92	34	18	28	12
CARD	6	100%	OTR110	6	6	0	0	0	OTR110	0	0	0	0	0
WALG	(16)	57%	OTR110	12	0	6	6	0	OTR110	28	12	4	9	3
<b>TI OXY</b>	<b>(123)</b>	<b>34%</b>	<b>TI OXY</b>	<b>238</b>	<b>56</b>	<b>56</b>	<b>87</b>	<b>39</b>	<b>TI OXY</b>	<b>361</b>	<b>107</b>	<b>96</b>	<b>95</b>	<b>63</b>
CARD	6	50%	DIL810	12	3	3	2	4	DIL810	6	2	3	1	0
CARD	(3)	100%	DIL810	0	0	0	0	0	DIL810	3	0	0	1	2
<b>TI DIL</b>	<b>3</b>	<b>33%</b>	<b>TI DIL</b>	<b>12</b>	<b>3</b>	<b>3</b>	<b>2</b>	<b>4</b>	<b>TI DIL</b>	<b>9</b>	<b>2</b>	<b>3</b>	<b>2</b>	<b>2</b>
CARD	2	100%	BUP420	2	0	0	0	2	BUP420	0	0	0	0	0
CARD	2	100%	BUP410	2	0	0	0	2	BUP410	0	0	0	0	0
WALG	1	100%	BUP410	1	0	1	0	0	BUP410	0	0	0	0	0
<b>TI BUP</b>	<b>5</b>	<b>100%</b>	<b>TI BUP</b>	<b>5</b>	<b>0</b>	<b>1</b>	<b>0</b>	<b>4</b>	<b>TI BUP</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

# Account vs. State/National Averages (as of 3/31/13)

Outlet (DEA): BW6456493

Outlet Name: WALGREENS DRUG 04240

Outlet State: WI

OxyContin					
WALGREENS DRUG 04240 BW6456493	Pills	WI	Pills	National	Pills
OxyContin 10mg	1,300	OxyContin 10mg	2,244,100	OxyContin 10mg	73,872,300
OxyContin 15mg	700	OxyContin 15mg	335,000	OxyContin 15mg	11,499,100
OxyContin 20mg	1,800	OxyContin 20mg	2,524,700	OxyContin 20mg	104,497,300
OxyContin 30mg	1,800	OxyContin 30mg	844,700	OxyContin 30mg	40,422,300
OxyContin 40mg	1,900	OxyContin 40mg	1,738,300	OxyContin 40mg	91,188,900
OxyContin 60mg	1,400	OxyContin 60mg	668,600	OxyContin 60mg	35,084,700
OxyContin 80mg	2,000	OxyContin 80mg	1,303,100	OxyContin 80mg	80,889,400

Butrans					
WALGREENS DRUG 04240 BW6456493	Patches	WI	Patches	National	Patches
Butrans 10 mcg/hour	12	Butrans 10 mcg/hour	19,912	Butrans 10 mcg/hour	936,128
Butrans 20 mcg/hour	4	Butrans 20 mcg/hour	9,984	Butrans 20 mcg/hour	641,708
Butrans 5 mcg/hour	0	Butrans 5 mcg/hour	8,232	Butrans 5 mcg/hour	529,588

Dilaudid					
WALGREENS DRUG 04240 BW6456493	Pills	WI	Pills	National	Pills
Dilaudid 2mg	0	Dilaudid 2mg	700	Dilaudid 2mg	567800
Dilaudid 4mg	0	Dilaudid 4mg	8000	Dilaudid 4mg	4806500
Dilaudid 8mg	1900	Dilaudid 8mg	3100	Dilaudid 8mg	1383400

# Information beyond Data

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- ❑ Collaboration with wholesalers/distributors:
  - ❑ In person meetings with authorized wholesaler
  - ❑ Regularly-scheduled calls to share information
  - ❑ Occasional joint site visits
- ❑ Review publicly available information on accounts
- ❑ Seek input from Purdue field-based sales personnel
  - ❑ Have information from prescriber analysis
- ❑ Create individual reports on accounts reviewed
  - ❑ Discuss reviewed accounts at OMS Committee meetings
- ❑ Track all actions in OMS database

# Lessons Learned

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- ❑ Quantities matter: excessive orders must be evaluated
- ❑ Meaningful scrutiny of dispensing: registration not sufficient
- ❑ Site visit due diligence: expected as part of follow up
- ❑ Cannot rely on third party: must do own due diligence
- ❑ Trend analysis is a key: compare similar products, size and location of outlets
- ❑ Threshold exceptions: must be individually reviewed and decisions properly documented
- ❑ Referrals to DEA: consider for all OMS actions

# Lessons Learned

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- ❑ Experience with ORF
  - ❑ Declines versus increased orders
- ❑ Real patient harm from broad restrictions
  - ❑ Patient feedback
- ❑ Consideration given to isolating high utilization of currently abused products (IR 30mg)?
- ❑ Considerations of segregation of products with labeling for abuse deterrence?

# Benefits of Collaboration

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- ❑ Greater information sharing: maximize resources (Wholesaler, Manufacturer, Distributor, Retail Chains)
- ❑ Help identify potentially problematic prescribers
- ❑ Develop process to address patient complaints and concerns
- ❑ Achieve efficiencies with accounts identified for follow up
- ❑ Identify additional tools to address DEA's concerns (better data analysis, potential modeling)
- ❑ Mindful of anti-trust concerns



# Mutual Support

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- ❑ Identify contact OMS representative
- ❑ Communicate on regular basis
- ❑ Collaborate to identify suspicious accounts, coordinate follow up (if appropriate)
- ❑ Leverage each other's data as permitted
- ❑ Provide OMS contact with prescriber-related information
- ❑ Report suspicious accounts to DEA